State of Utah
Administrative Rule Analysis

NOTICE OF PROPOSED RULE

* The agency identified below in box 1 provides notice of proposed rule change pursuant to Utah Code Section 63G-3-301.
* Please address questions regarding information on this notice to the agency.
* The full text of all rule filings is published in the Utah State Bulletin unless excluded because of space constraints.
* The full text of all rule filings may also be inspected at the Division of Administrative Rules.

DAR file no:		Date filed:	
State Admin Rule Filing Id:		Time filed:	

		Agency No.		Rule No.		Section No.
Utah Admin. Code Ref (R no.):	**R**	156	**-**	17b	**-**	102
Changed to Admin. Code Ref. (R no.):	**R**		**-**		**-**	

1. **Agency:** Commerce/Division of Occupational and Professional Licensing

Room no.:	
Building:	Heber M. Wells Building
Street address 1:	160 East 300 South
Street address 2:	
City, state, zip:	Salt Lake City UT 84111-2316
Mailing address 1:	PO Box 146741
Mailing address 2:	
City, state, zip:	Salt Lake City UT 84114-6741

Contact person(s):

Name:	**Phone:**	**Fax:**	**E-mail:**
Debra Hobbins	801-530-6789	801-530-6511	dhobbins@utah.gov

(Interested persons may inspect this filing at the above address or at the Division of Administrative Rules during business hours)

2. **Title of rule or section** (catchline)**:**

Definitions

3. **Type of notice:**

New ___; Amendment XX; Repeal ___; Repeal and Reenact ___

4. **Purpose of the rule or reason for the change:**

The Division needs to update the United States Pharmacopeia-National Formulary (USP-NF) books which are incorporated by reference to the most current edition available.

5. **This change is a response to comments from the Administrative Rules Review Committee.**

No XX; Yes ___

6. **Summary of the rule or change:**

In paragraph (41) updated the USP-NF books to the USP34-NF29, 2011 edition, which is official from May 1, 2011 through Supplement 1, dated August 1, 2011.

7. **Aggregate anticipated cost or savings to:**

A) State budget:

Affected:	No ___; Yes XX

	The Division will incur minimal costs of approximately $75.00 to print and distribute the rule once the proposed amendments are made effective. Any costs incurred will be absorbed in the Division's current budget. The Division also incurs a yearly expense of approximately $1,725 to purchase two copies of the referenced books, one copy for Division use and one copy to be sent to Division of Administrative Rules.	
	B) Local government:	
	Affected:	No XXX; Yes ___
	Proposed amendment is only updating a series of books which are incorporated by reference and are used by the pharmacy profession. As a result, proposed amendment does not affect local governments.	
	C) Small businesses ("small business" means a business employing fewer than 50 persons)**:**	
	Affected:	No ___; Yes XX
	Licensed pharmacies, some of which may qualify as a small business, who are required to maintain a copy of the current edition of the USP-NF books will incur a cost of approximately $860 per year to update their subscription..	
	D) Persons other than small businesses, businesses, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an agency)**:**	
	Affected:	No ___; Yes XX
	Licensed pharmacies who are required to maintain a copy of the current edition of the USP-NF books will incur a cost of approximately $860 per year to update their subscription. There are currently 1,435 licensed pharmacies (Class A through Class E) for an aggregate yearly cost of $1,234,100.	
8.	**Compliance costs for affected persons:**	
	Licensed pharmacies who are required to maintain a copy of the current edition of the USP-NF books will incur a cost of approximately $860 per year to update their subscription.	
9.	**A) Comments by the department head on the fiscal impact the rule may have on businesses:**	
	This rule filing updates references to the most current edition of the pharmacopoeia formulary. No fiscal impact to businesses is anticipated beyond those described in the rule summary.	
	B) Name and title of department head commenting on the fiscal impacts:	
	Francine A. Giani, Executive Director	
10.	**This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws.** **State code or constitution citations (required)** (e.g., Section 63G-3-402; Subsection 63G-3-601(3); Article IV) **:**	
	Section 58-17b-101	Subsection 58-17b-601(1)
	Section 58-37-1	Subsection 58-1-106(1)(a)
	Subsection 58-1-202(1)(a)	

11. **This rule adds, updates, or removes the following title of materials incorporated by references** (a copy of materials incorporated by reference must be submitted to the Division of Administrative Rules; *if none, leave blank*)**:**

	First Incorporation	**Second Incorporation**
Official Title of Materials Incorporated (from title page)	United States Pharmacopeia-National Formulary (USP 34-NF 29) through Supplement 1	
Publisher	U.S. Pharmacopeia	
Date Issued		
Issue, or version	May 1, 2011 and August 1, 2011	
ISBN Number (optional)		
ISSN Number (optional)		
Cost of Incorporated Reference	$860.00	
Action: Adds, updates, or removes	Updates	

(If this rule incorporates more than two items by reference, please attach additional pages)

12.	**The public may submit written or oral comments to the agency identified in box 1.** (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)		
	A) Comments will be accepted until 5:00 p.m. on (mm/dd/yyyy)**:**		11/14/2011
	B) A public hearing (optional) will be held:		
	On (mm/dd/yyyy)**:**	**At** (hh:mm AM/PM)**:**	**At** (place)**:**
13.	**This rule change may become effective on** (mm/dd/yyyy)**:**		11/21/2011
	NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 12(A) above, the agency must submit a Notice of Effective Date to the Division of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.		
14.	**Indexing information -- keywords** (maximum of four, in lower case, except for acronyms (e.g., "GRAMA") or proper nouns (e.g., "Medicaid"); may not include the name of the agency**:**		
	pharmacists	licensing	
	pharmacies		
15.	**Attach an RTF document containing the text of this rule change** (filename)**:**		R156-17b.pro

To the agency: Information requested on this form is required by Sections 63G-3-301, 302, 303, and 402. Incomplete forms will be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin*, and delaying the first possible effective date.

AGENCY AUTHORIZATION

Agency head or designee, and title:	Mark B. Steinagel, Director	**Date** (mm/dd/yyyy)**:**	09/20/2011

R156. Commerce, Occupational and Professional Licensing.
R156-17b. Pharmacy Practice Act Rule.
R156-17b-102. Definitions.

In addition to the definitions in Title 58, Chapters 1 and 17b, as used in Title 58, Chapters 1 and 17b or this rule:

(1) "ACPE" means the American Council on Pharmaceutical Education or Accreditation Council for Pharmacy Education.

(2) "Analytical laboratory":

(a) means a facility in possession of prescription drugs for the purpose of analysis; and

(b) does not include a laboratory possessing prescription drugs used as standards and controls in performing drug monitoring or drug screening analysis if the prescription drugs are pre-diluted in a human or animal body fluid, human or animal body fluid components, organic solvents, or inorganic buffers at a concentration not exceeding one milligram per milliliter when labeled or otherwise designated as being for in-vitro diagnostic use.

(3) "Authorized distributor of record" means a pharmaceutical wholesaler with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drugs. An ongoing relationship is deemed to exist between such pharmaceutical wholesaler and a manufacturer, as defined in Section 1504 of the Internal Revenue Code, when the pharmaceutical wholesaler has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship, and the pharmaceutical wholesaler is listed on the manufacturer's current list of authorized distributors of record.

(4) "Authorized personnel" means any person who is a part of the pharmacy staff who participates in the operational processes of the pharmacy and contributes to the natural flow of pharmaceutical care.

(5) "Central Order Entry" means a pharmacy where functions are performed at the request of another pharmacy to perform processing functions such as dispensing, drug review, refill authorizations, and therapeutic interventions.

(6) "Chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of the prescription drugs to a group of chain pharmacies that have the same common ownership and control.

(7) "Co-licensed partner or product" means an instance where two or more parties have the right to engage in the manufacturing and/or marketing of a prescription drug, consistent with FDA's implementation of the Prescription Drug Marketing Act.

(8) "Cooperative pharmacy warehouse" means a physical location for drugs that acts as a central warehouse and is owned, operated or affiliated with a group purchasing organization (GPO) or pharmacy buying cooperative and distributes those drugs exclusively to its members.

(9) "Counterfeit prescription drug" has the meaning given that term in 21 USC 321(g)(2), including any amendments thereto.

(10) "Counterfeiting" means engaging in activities that create a counterfeit prescription drug.

(11) "Dispense", as defined in Subsection 58-17b-102(23), does not include transferring medications for a patient from a legally dispensed prescription for that particular patient into a daily or weekly drug container to facilitate the patient taking the correct medication.

(12) "Drop shipment" means the sale of a prescription drug to a pharmaceutical wholesaler by the manufacturer of the drug; by the manufacturer's co-licensed product partner, third party logistics provider, or exclusive distributor; or by an authorized distributor of record that purchased the product directly from the manufacturer or from one of these entities; whereby:

(a) the pharmaceutical wholesale distributor takes title to but not physical possession of such prescription drug;

(b) the pharmaceutical wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense to administer such drug; and

(c) the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer such drug receives delivery of the prescription drug directly from the manufacturer; from the co-licensed product partner, third party logistics provider, or exclusive distributor; or from an authorized distributor of record that purchases the product directly from the manufacturer or from one of these entities.

(13) "Drug therapy management" means the review of a drug therapy regimen of a patient by one or more pharmacists for the purpose of evaluating and rendering advice to one or more practitioners regarding adjustment of the regimen.

(14) "Drugs", as used in this rule, means drugs or devices.

(15) "ExCPT", as used in this rule, means the Exam for the Certification of Pharmacy Technicians.

(16) "FDA" means the United States Food and Drug Administration and any successor agency.

(17) "High-risk, medium-risk, and low-risk drugs" refers to the risk to a patient's health from compounding sterile preparations, as referred to in USP-NF Chapter 797, for details of determining risk level.

(18) "Hospice facility pharmacy" means a pharmacy that supplies drugs to patients in a licensed healthcare facility for terminal patients.

(19) "Hospital clinic pharmacy" means a pharmacy that is located in an outpatient treatment area where a pharmacist or pharmacy intern is compounding, admixing, or dispensing prescription drugs, and where:

(a) prescription drugs or devices are under the control of the pharmacist, or the facility for administration to patients of that

facility;

(b) prescription drugs or devices are dispensed by the pharmacist or pharmacy intern; or

(c) prescription drugs are administered in accordance with the order of a practitioner by an employee or agent of the facility.

(20) "Legend drug" or "prescription drug" means any drug or device that has been determined to be unsafe for self-medication or any drug or device that bears or is required to bear the legend:

(a) "Caution: federal law prohibits dispensing without prescription";

(b) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(c) "Rx only".

(21) "Maintenance medications" means medications the patient takes on an ongoing basis.

(22) "Manufacturer's exclusive distributor" means an entity that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the drug's sale or disposition. Such manufacturer's exclusive distributor must be licensed as a pharmaceutical wholesaler under this chapter and be an "authorized distributor of record" to be considered part of the "normal distribution channel".

(23) "MPJE" means the Multistate Jurisprudence Examination.

(24) "NABP" means the National Association of Boards of Pharmacy.

(25) "NAPLEX" means North American Pharmacy Licensing Examination.

(26) "Normal distribution channel" means a chain of custody for a prescription drug that goes directly, by drop shipment as defined in Subsection (12), or via intracompany transfer from a manufacturer; or from the manufacturer's co-licensed partner, third-party logistics provider, or the exclusive distributor to:

(a) a pharmacy or other designated persons authorized under this chapter to dispense or administer prescription drugs to a patient;

(b) a chain pharmacy warehouse that performs intracompany sales or transfers of such drugs to a group of pharmacies under common ownership and control;

(c) a cooperative pharmacy warehouse to a pharmacy that is a member of the pharmacy buying cooperative or GPO to a patient;

(d) an authorized distributor of record, and then to either a pharmacy or other designated persons authorized under this chapter to dispense or administer such drug for use by a patient;

(e) an authorized distributor of record, and then to a chain pharmacy warehouse that performs intracompany sales or transfers of such drugs to a group of pharmacies under common ownership and control; or

(f) an authorized distributor of record to another authorized distributor of record to a licensed pharmaceutical facility or a licensed healthcare practitioner authorized under this chapter to dispense or administer such drug for use by a patient.

(27) "Parenteral" means a method of drug delivery injected into body tissues but not via the gastrointestinal tract.

(28) "Pedigree" means a document or electronic file containing information that records each distribution of any given prescription drug.

(29) "PIC", as used in this rule, means the pharmacist-in-charge.

(30) "Prescription files" means all hard-copy and electronic prescriptions that includes pharmacist notes or technician notes, clarifications or information written or attached that is pertinent to the prescription.

(31) "PTCB" means the Pharmacy Technician Certification Board.

(32) "Qualified continuing education", as used in this rule, means continuing education that meets the standards set forth in Section R156-17b-309.

(33) "Refill" means to fill again.

(34) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug, excluding that completed by the pharmacist responsible for dispensing the product to a patient.

(35) "Reverse distributor" means a person or company that retrieves unusable or outdated drugs from a pharmacy or pharmacist for the purpose of removing those drugs from stock and destroying them.

(36) "Sterile products preparation facility" means any facility, or portion of the facility, that compounds sterile products using aseptic technique.

(37) "Third party logistics provider" means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but does not take title to the prescription drug or have any authoritative control over the prescription drug's sale. Such third party logistics provider must be licensed as a pharmaceutical wholesaler under this chapter and be an "authorized distributor of record" to be considered part of the "normal distribution channel".

(38) "Unauthorized personnel" means any person who is not participating in the operational processes of the pharmacy who in some way would interrupt the natural flow of pharmaceutical care.

(39) "Unit dose" means the ordered amount of a drug in a dosage form prepared for a one-time administration to an individual and indicates the name, strength, lot number and expiration date for the drug.

(40) "Unprofessional conduct", as defined in Title 58, Chapters 1 and 17b, is further defined, in accordance with

Subsection 58-1-203(1)(e), in Section R156-17b-502.

(41) "USP-NF" means the United States Pharmacopeia-National Formulary (USP [~~32~~]34-NF [~~27~~]29), [~~2009~~]2011 edition, which is official from May 1, [~~2009~~]2011 through Supplement [~~2~~]1, dated [~~December 1, 2009~~]August 1, 2011, which is hereby adopted and incorporated by reference.

(42) "Wholesaler" means a wholesale distributor who supplies or distributes drugs or medical devices that are restricted by federal law to sales based on the order of a physician to a person other than the consumer or patient.

(43) "Wholesale distribution" means the distribution of drugs to persons other than consumers or patients, but does not include:

(a) intracompany sales or transfers;

(b) the sale, purchase, distribution, trade, or other transfer of a prescription drug for emergency medical reasons, as defined under 21 CFR 203.3(m), including any amendments thereto;

(c) the sale, purchase, or trade of a drug pursuant to a prescription;

(d) the distribution of drug samples;

(e) the return or transfer of prescription drugs to the original manufacturer, original wholesale distributor, reverse distributor, or a third party returns processor;

(f) the sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record during a time period for which there is documentation from the manufacturer that the manufacturer is able to supply a prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel;

(g) the sale, purchase or exchange of blood or blood components for transfusions;

(h) the sale, transfer, merger or consolidation of all or part of the business of a pharmacy;

(i) delivery of a prescription drug by a common carrier; or

(j) other transactions excluded from the definition of "wholesale distribution" under 21 CFR 203.3 (cc), including any amendments thereto.

KEY: pharmacists, licensing, pharmacies
Date of Enactment or Last Substantive Amendment: [~~July 26, ~~]2011
Notice of Continuation: February 23, 2010
Authorizing, and Implemented or Interpreted Law: 58-17b-101; 58-17b-601(1); 58-37-1; 58-1-106(1)(a); 58-1-202(1)(a)